

section and stating the starting and finishing dates of the research for which the confidentiality of identity of research subjects was granted; upon receipt of this letter, the research shall return the original letter of exemption.

[42 FR 54946, Oct. 12, 1977. Redesignated at 54 FR 31670, Aug. 1, 1989, as amended at 62 FR 13970, Mar. 24, 1997]

§ 1316.24 Exemption from prosecution for researchers.

(a) Upon registration of an individual to engage in research in controlled substances under the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801), the Administrator of the Drug Enforcement Administration, on his own motion or upon request in writing from the Secretary or from the researcher or researching practitioner, may exempt the registrant when acting within the scope of his registration, from prosecution under Federal, State, or local laws for offenses relating to possession, distribution or dispensing of those controlled substances within the scope of his exemption. However, this exemption does not diminish any requirement of compliance with the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301).

(b) All petitions for Grants of Exemption from Prosecution for the Researcher shall be addressed to the Administrator, Drug Enforcement Administration, 1405 I Street NW., Washington, DC 20537 and shall contain the following:

- (1) The researcher's registration number if any, for the project;
- (2) The location of the research project;
- (3) The qualifications of the principal investigator;
- (4) A general description of the research or a copy of the research protocol;
- (5) The source of funding for the research project;
- (6) A statement as to the risks posed to the research subjects by the research procedures and what protection will be afforded to the research subjects;
- (7) A statement as to the risks posed to society in general by the research procedures and what measures will be

taken to protect the interests of society;

(8) A specific request for exemption from prosecution by Federal, State, or local authorities for offenses related to the possession, distribution, and dispensing of controlled substances in accord with the procedures described in the research protocol;

(9) A statement establishing that a grant of exemption from prosecution is necessary to the successful completion of the research project.

(c) Any researcher or practitioner proposing to engage in research requesting both exemption from prosecution and confidentiality of identity of research subjects may submit a single petition incorporating the information required in §§ 1316.23(b) and 1316.24(b).

(d) The exemption shall consist of a letter issued by the Administrator, which shall include:

- (1) The researcher's name and address;
- (2) The researcher's registration number for the research project;
- (3) The location of the research project;
- (4) A concise statement of the scope of the researcher's registration;
- (5) Any limits of the exemption; and
- (6) A statement that the exemption shall apply to all acts done in the scope of the exemption while the exemption is in effect. The exemption shall remain in effect until completion of the research project or until the registration of the researcher is either revoked or suspended or his renewal of registration is denied. However, the protection afforded by the grant of exemption from prosecution during the research period shall be perpetual.

(e) Within 30 days of the date of completion of the research project, the researcher shall so notify the Administrator. The Administrator shall issue another letter including the information required in paragraph (d) of this section and stating the date of which the period of exemption concluded; upon receipt of this letter the researcher shall return the original letter of exemption.

[42 FR 54946, Oct. 12, 1977. Redesignated at 54 FR 31670, Aug. 1, 1989, as amended at 62 FR 13970, Mar. 24, 1997]